UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,624	01/26/2004	Michael Benser	A04P1008	2273

36802 7590 03/04/2008

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
RIUTTA, ANDERS	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
03/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,624	BENSER ET AL.	
	Examiner	Art Unit	
	ANDERS RIUTTA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,18-32,34 and 35* is/are pending in the application.

4a) Of the above claim(s) *31,32 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,18-30 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/06/2007, 12/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Art Unit: 3762

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-11, 18-30, and 35 in the reply filed on 12/06/2007 is acknowledged.

2. Claims 31, 32, and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/06/2007.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-9 and 19-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 20-31 of copending Application No. 10/765625. Independent claims 1 and 19 of the instant application differ from independent claims 1 and 20 of copending Application No. 10/765625 only in reciting a nondecreasing monotonic relationship instead of the nonincreasing monotonic relationship recited in copending Application No. 10/765625. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 19 of the instant application are anticipated by claims 1 and 20, respectively, of copending Application No. 10/765625 since both an increasing and a decreasing monotonic relationship would anticipate a constant relationship and anticipation is the epitome of obviousness. Dependent claims 2-9 and 21-30 of the instant application are identical in substance to claims 2-9 and 22-31 (respectively) of copending Application No. 10/765625. Claim 19 of the instant application differs from claim 21 of copending Application No. 10/765625 in reciting "increasing tidal volume" instead of "decreasing difference between the tidal volume and the limit." Because tidal volume is recited as being less than the limit, increasing tidal volume is the same as decreasing difference between tidal volume and the limit.

Art Unit: 3762

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-3, 6-9, 19-27, and 30 are rejected under 35 U.S.C. 102(b) as being unpatentable over Scheiner (US 6,415,183).

Regarding claims 1, 8, 9, and 19, Scheiner discloses the same invention substantially as claimed, including sensing minute ventilation (abstract), which is related to tidal volume (Col. 5, lines 47-48), a

microprocessor determining if the tidal volume is less than a limit (Figure 2; Col. 6, lines 19-21), and calling for diaphragm activation (abstract; Col. 6, lines 19-21) with a constant stimulation power, a constant relationship being one form of a nondecreasing monotonic relationship (Col. 4, line 66 through Col. 5, line 1).

Regarding claim 2, Scheiner further discloses phrenic nerve stimulation (abstract).

Regarding claim 3, Scheiner further discloses delivering activation (abstract).

Regarding claims 6 and 22, Scheiner further discloses the limit relies on historical respiratory information unaffected by CSR (Col. 5, lines 44-62; Col. 6, lines 57-65).

Regarding claims 7 and 21, Scheiner further discloses impedance information (Col. 5, lines 44-63).

Regarding claim 20, Scheiner further discloses a connector (Figure 1A).

Regarding claim 23, Scheiner further discloses a pulse generator (Figure 1A, Element 170).

Regarding claim 24, Scheiner further discloses an output (Figure 1A and Figure 2, Element 225).

Regarding claim 25, Scheiner further discloses a connector (Figure 1A).

Regarding claims 26 and 27, Scheiner further discloses a pulse generator (Figure 1A, Element 170) and a lead (Figure 1A, Elements 120, 130, 140, and 150).

Regarding claim 30, Scheiner further discloses a cardiac stimulation output (Figure 1A; Col. 2, lines 10-27).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 5, 10, 11, 18, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner as applied to claims 1, 3, and 19 above, in view of Meer (US 4,830,008).

Regarding claim 5, Scheiner as applied to claim 3 is described above. Scheiner does not disclose monitoring upper airway patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Scheiner, in order to provide the predictable result of preventing upper airway collapse.

Regarding claims 10 and 11, Scheiner as applied to claim 1 is described above. Scheiner does not disclose monitoring upper airway

patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Scheiner, in order to provide the predictable result of preventing upper airway collapse.

Regarding claim 18, Scheiner discloses sensing minute ventilation (abstract), which is related to tidal volume (Col. 5, lines 47-48); determining if tidal volume is less than a limit (Figure 2; Col. 6, lines 19-21); and calling for diaphragm activation with a constant stimulation power, a constant relationship being one form of a nondecreasing monotonic relationship (Col. 4, line 66 through Col. 5, line 1). Scheiner does not disclose monitoring upper airway patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Scheiner, in order to provide the predictable result of preventing upper airway collapse.

Regarding claims 28 and 29, Scheiner as applied to claim 19 is described above. Scheiner does not disclose an input to receive information on upper airway patency. However, Meer teaches a monitor 14 for

monitoring upper airway patency (Fig. 1 and Col. 4, lines 5-15), in order to prevent upper airway collapse (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitor of Meer with the invention of Scheiner, in order to provide the predictable result of preventing upper airway collapse.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner as applied to claim 3 above, in view of Ottenhoff (US 6,251,126). Regarding claim 4, Scheiner as applied to claim 3 is described above. Scheiner does not disclose delivering the activation during inspiration caused in part by intrinsic activity. However, Ottenhoff teaches delivering the activation during inspiration caused in part by intrinsic activity (Figure 5A; Figure 6, Elements 52 and 53; and Col. 2, lines 39-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the synchronization of Ottenhoff with the invention of Scheiner, in order to provide the predictable result of treating dyspnea.

12. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tehrani (US 2005/0085865). Regarding claim 35, Tehrani discloses sensing respiratory information related to tidal volume (Paragraphs 11, 12; Paragraph 41, Line 6); determining if hyperventilation or hypoventilation is occurring (Figure 9C; Paragraphs 16, 71, 73); and calling for diaphragm activation based on a nonincreasing monotonic relationship or a

nondecreasing monotonic relationship to tidal volume (Paragraphs 41, 58; Fig. 10B: element 561). A constant relationship is an example of both a nondecreasing and a nonincreasing monotonic relationship. Because Tehrani discloses calculating tidal volume (Paragraph 71), it would have been obvious to one of ordinary skill in the art at the time the invention was made to calculate two tidal volume limits instead of hyperventilation or hypoventilation in order to provide the predictable result of a target range for tidal volume during therapy.

Response to Arguments

13. Applicant's arguments filed 12/06/2007 have been fully considered but they are not persuasive. The argument that Scheiner does not teach a monotonic relationship because the term "monotonic" does not include constant relationships is not persuasive since "monotonic" can also mean "having the property either of never increasing or of never decreasing as the values of the independent variable or the subscripts of the terms increase." Merriam-Webster's Online Dictionary, http://www.m-w.com, accessed February 19, 2008. Therefore Scheiner meets the limitation of monotonic because although applicant has provided one definition of monotonic, this is not the only definition of monotonic (as seen above). It is suggested to amend the claims to specifically recite what is meant by nondecreasing and nonincreasing monotonic.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDERS RIUTTA whose telephone number is (571) 270-3514. The examiner can normally be reached on Monday through Friday, 9:00AM to 5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. R./
Examiner, Art Unit 3762
/George R Evanisko/
Primary Examiner, Art Unit 3762